UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

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| ROBERT REID, on behalf of himself and all others similarly situated,<br><br>Plaintiff,<br><br>v.<br><br>JOHNSON & JOHNSON and McNEIL NUTRITIONALS, LLC,<br><br>Defendants. | Civil No. 11cv1310 L (BLM)<br><br>**ORDER GRANTING IN PART DEFENDANTS' MOTION TO DISMISS AND DENYING MOTION TO STRIKE [doc. #11] and DENYING PLAINTIFF's REQUEST FOR JUDICIAL NOTICE [doc. #17]** |

Robert Reid ("Plaintiff") brings this class action against Johnson & Johnson and McNeil Nutritionals, LLC, ("Defendants"). Defendants move to dismiss, or in the alternative, to strike portions of the complaint. The Court has jurisdiction pursuant to 28 U.S.C. § 1332(d)(2) (The Class Action Fairness Act).

## I. BACKGROUND

Johnson & Johnson manufactures and sells Benecol Spread and Benecol Light Spread ("Benecol"). (Compl. ¶ 2 [Doc. 1].) Benecol is a margarine-like, vegetable-oil-based spread sold in eight-ounce tubs with the following labels: "Proven to Reduce Cholesterol"; "No Trans Fat"; "No Trans Fatty Acids"; and "Each serving contains .85 g of Plant Stanol Esters." (*Id.* ¶ 2; Ex. A; Ex. B; Ex. C.)

Plaintiff initially purchased Benecol about four years prior to filing the complaint and has

made several purchases until about five months before he filed this complaint on June 14, 2011. (*Id.* ¶ 113.) Plaintiff alleges that in spite of Benecol's expensive price, he purchased it in reliance of its representations that (1) plant stanol esters may reduce the risk for coronary heart disease; (2) Benecol is proven to reduce cholesterol; and (3) Benecol contains no trans fat or trans fatty acids. (*Id.* ¶ 114.)

First, Plaintiff alleges that Benecol's health claims concerning plant stanol esters are false and that it is therefore misbranded for the following reasons: (1) Benecol does not contain sufficient plant stanol esters per serving; (2) Benecol does not contain the minimum amount of vitamin A required prior to any nutrient addition; and (3) Benecol's label contains an inaccurate level of recommended consumption of plant stanol esters pursuant to federal law. (*Id.* ¶¶ 78, 82, 85–86.)

Second, Plaintiff alleges that Benecol's claim that it is "Proven to Reduce Cholesterol" is false and misleading because no studies support the claim that Benecol – as formulated – effectively reduces blood cholesterol. (*Id.* ¶ 94.) Plaintiff, however, concedes that studies have shown that plant stanol esters, in certain forms, may reduce LDL cholesterol. (*Id.* ¶ 94.) Additionally, Plaintiff alleges that the claim "Proven to Reduce Cholesterol" renders Benecol an improperly-marked drug because it portrays Benecol as a product made to affect the structure or function of the body by "reduc[ing] 'bad' (LDL) cholesterol" and "reduc[ing] total cholesterol." (*Id.* ¶ 102.)

Third, Plaintiff alleges that Benecol is misbranded due to its "no trans fat" and "no trans fatty acids" labels. (*Id.* ¶¶ 108–11.) While the Food and Drug Administration ("FDA") permits the use of defined nutrient content claims, the FDA has not yet defined "no trans fat" and "no trans fatty acids." Plaintiff also asserts that these claims are false because Benecol actually contains small amounts of artificial trans fatty acids. (*Id.* ¶ 112.)

In addition to the above allegations, Plaintiff cites numerous scientific studies that describe the role of cholesterol in heart disease and the health hazards that artificial trans fat may cause, such as increasing the risk of cardiovascular heart disease and causing type 2 diabetes and cancer. (*Id.* ¶¶ 17–66).

Plaintiff asserts four causes of action against Defendants: (1) unlawful business practices in violation of the California Unfair Competition Law ("UCL"); (2) unfair and fraudulent business practices in violation of the UCL; (3) violations of the California False Advertising Law ("FAL"); and (4) violations of the Consumer Legal Remedies Act ("CLRA").

## II. DISCUSSION

In their Motion to Dismiss, Defendants contend that Plaintiff's claims are barred under three theories: (1) preemption by the FDA's Nutrition Labeling and Education Act ("NLEA"); (2) primary jurisdiction; and (3) judicial abstention. Defendants also argue that Plaintiff lacks standing to sue under the UCL and FAL because his complaint does not adequately plead reliance. In the alternative, Defendants move to strike certain portions of the complaint. Plaintiff opposes and requests that the Court take judicial notice of sixteen exhibits.

### A. Standing Under the UCL, FAL, and CLRA

"The California Supreme Court has recognized that [the UCL, FAL, and CLRA] prohibit not only advertising which is false, but also advertising which, although true, is either actually misleading or which has a capacity, likelihood, or tendency to deceive or confuse the public." *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 938 (9th Cir. 2008). As a threshold matter, a plaintiff must allege that the allegedly false and misleading statements were "likely to deceive a reasonable consumer." *Consumer Advocates v. EchoStar Satellite Corp.*, 113 Cal. App. 4th 1351, 1361–62 (2003). A "reasonable consumer" is an ordinary consumer who acts reasonably in light of all the circumstances. *See Freeman v. Time, Inc*. 68 F.3d 285, 289 (9th Cir. 1995). In addition, a plaintiff must plead that he actually relied on the alleged misrepresentation. *See In re Tobacco II Cases*, 46 Cal.4th 298 (2009); *Chacanaca v. Quaker Oats Co.*, 752 F.Supp.2d 1111, 1124–25 (N.D. Cal.2010). "California courts . . . have recognized that whether a business practice is deceptive will usually be a question of fact not appropriate for a decision on [a motion to dismiss]." *Williams v. Gerber Products Co.*, 552 F.3d 934, 938 (9th Cir. 2008).

California's UCL prohibits "any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." CAL. BUS. & PROF. CODE § 17200. "Any violation of the false advertising law" also violates the UCL. *Williams*, 552 F.3d at 938

(internal citations omitted). In a UCL claim, "a plaintiff suffers 'injury in fact' for the purposes of standing when he or she has: "(1) expended money due to the defendant's acts of unfair competition; (2) lost money or property; or (3) been denied money to which he or she has a cognizable claim." *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1125 (2010).

California's FAL also prohibits "unfair or fraudulent business acts or practices and unfair, deceptive, untrue or misleading advertising." CAL. BUS. & PROF. CODE § 17500. For FAL claims, "courts in California require that plaintiffs demonstrate the purchase of products as a result of deceptive advertising." *Chacanaca*, 752 F. Supp. 2d at 1125.

The CLRA prohibits "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale or lease of goods or services to any consumer." CAL. CIV. CODE § 1770(a). The CLRA requires actual reliance by the plaintiff for standing purposes. *See* CAL. CIV. CODE § 1780(a); *Buckland v. Threshold Enters., Ltd.*, 155 Cal. App. 4th 798, 810 (2007), disapproved of on other grounds by *Kwikset Corp. v. Super. Ct.*, 51 Cal. 4th 310 (2011) ("[P]laintiffs asserting CLRA claims sounding in fraud must establish that they actually relied on the relevant representations or omissions.").

**1. Legal Standard Under Rule 9(b)**

Federal Rule of Civil Procedure 8(a) typically governs pleading requirements and requires that a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a). However, a claim sounding in fraud is subject to Rule 9(b)'s heightened pleading requirement that plaintiff "state with particularity the circumstances constituting fraud." FED. R. CIV. P. 9(b). "It is established law, in this circuit and elsewhere, that Rule 9(b)'s particularity requirement applies to state-law causes of action." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1103 (9th Cir. 2009). Thus, all three state law claims are required to be pleaded with particularity because Plaintiff alleges that Defendants engaged in fraudulent labeling on their product. *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124–25 (9th Cir. 2009). Rule 9(b) requires that allegations of fraud be "specific enough to give defendants notice of the particular misconduct . . . so that they can defend against the charge and not just

deny that they have done anything wrong." *Vess*, 317 F.3d at 1106 (internal citations omitted). To satisfy Rule 9(b), Plaintiff must state the requisite "who, what, when, where, and how" of the misconduct he alleges. *See Kearns*, 567 F.3d at 1124 (internal citations omitted).

**1. Rule 9(b)'s Requirements and Establishing Injury**.

Plaintiff identifies Johnson & Johnson as the manufacturer and seller of Benecol and McNeil Nutritionals, LLC, as a wholly-owned subsidiary of Johnson & Johnson. In his complaint, plaintiff alleges Benecol does not contain the minimum requirement of plant stanol esters per serving necessary to make an FDA-approved health claim; Benecol's "Proven to Reduce Cholesterol" claim is misleading because the amount of trans fat it contains would negate its purported health claims; and because Benecol contains artificial trans fat, its "No Trans Fat" and "No Trans Fatty Acids" claims are false.

According to Plaintiff, for over a decade, Johnson & Johnson labeled Benecol with a plant stanol ester health claim, claimed that Benecol is "Proven to Reduce Cholesterol," and claimed that it contains "No Trans Fat" or "No Trans Fatty Acids." Plaintiff asserts that he began purchasing Benecol about four years ago because of the purportedly misleading statements appearing on Benecol's containers, website, print advertisements, and television commercials. Further, Plaintiff alleges that he sought a product that was generally healthy and did not contain toxic ingredients, and purchased Benecol instead of competing products because he believed its advertised health claims even though the price of Benecol was higher than other products.

Construing the allegations in the light most favorable to Plaintiff, the Court finds that Plaintiff has satisfied Rule 9(b)'s heightened pleading requirements.

**2. Reliance and a Reasonable Consumer.**

Plaintiff alleges that, "like all reasonable consumers," he trusts that "information conveyed on packaged food labels is truthful, accurate, complete, and fully in accordance and compliance with federal law." (*Id.* ¶ 130.) He also claims that in purchasing Benecol, he sought a product that would "lower and not negatively affect his LDL and total cholesterol levels" and one that "did not contain any toxic ingredients that would negatively affect his LDL, HDL, and total blood cholesterol levels and expose him to a greater risk of diabetes, cancer, and heart

disease." (*Id.* ¶ 127.) Like the consumer in *Chavez*, who "lost the full value of the price he paid . . . which he would not have paid had he known the truth about the geographic origin of the products," Plaintiff alleges that he "paid more for Benecol, and would have been willing to pay less, or nothing at all, if he had not been misled by the representations and practices." (*Id.* ¶ 134.) *See Chavez*, 340 Fed. Appx. 359 at 361. In addition, Plaintiff purchased Benecol over a period of at least three years "instead of competing products based on the false statements and misrepresentations described [on Benecol's labels]." (Compl. ¶ 134.)

But Defendants argue that Plaintiff lacks standing because he has not adequately pleaded reliance on any purported misrepresentations found on Benecol's packaging. (Def.'s Mem. Supp. Mot. Dismiss 21.) They correctly point out that Plaintiff has not alleged physical harm, *i.e.*, that he did not receive the health benefits Benecol advertised. (*Id.* 22.) Plaintiff has neither alleged that Benecol failed to lower his cholesterol nor that Benecol negatively affected his LDL or total cholesterol. (*Id.*) Under California law, the UCL, FAL, and CLRA do not require physical harm, as reliance on manufacturers' representations and financial harm sufficiently satisfy injury-in-fact for standing purposes. *See Chacanaca*, 752 F. Supp. 2d at 1125; *see also Buckland*, 155 Cal. App. 4th at 810. A plaintiff sufficiently satisfies injury-in-fact for FAL, UCL, and CLRA claims when he alleges that he would not have paid full price for a soft drink had the manufacturer not falsely represented that it bottled and produced the drink in New Mexico. *Chavez v. Blue Sky Natural Beverage Co.*, 340 Fed. Appx. 359, 361–62, WL 1956225 (2009).

Turning to whether a reasonable consumer reading that Benecol contains "Trans Fat 0g" in the nutrition facts panel and that it contains "partially hydrogenated soybean oil" in the list of ingredients pursuant to the FDA's requirements, the Court finds, even at the pleading stage, that it is not possible for the reasonable consumer to be deceived by Benecol's "No Trans Fat" and "No Trans Fatty Acids" labels. Benecol's ingredient list, although in smaller print than the larger font on the lid of Benecol's container and immediately above the nutrition facts panel, shows that it contains a small amount of partially hydrogenated oils and trans fats. A reasonable consumer would be unlikely to incorrectly interpret "No Trans Fat" to mean that Benecol

products do not contain any trans fat. Thus, the Court finds at this stage of the proceedings that Benecol's alleged misrepresentations would not likely deceive a reasonable consumer.

Although Plaintiff has alleged sufficiently that he suffered economic injury, he has not set forth alleged facts showing that Benecol's statements may deceive a reasonable consumer. Accordingly, the Court finds that Plaintiff has failed to satisfy the standing requirements under the UCL, FAL, and CLRA and the motion to dismiss for lack of standing will be granted. The Court will also consider whether preemption requires the complaint to be dismissed.

**B. Federal Preemption**

Federal law preempts state law when: (1) a congressional statute explicitly preempts state law (express preemption); (2) federal law occupies a legislative field to an extent that it is reasonable to conclude that Congress left no room for the state to regulate in that field (field preemption); or (3) state law conflicts with federal law (conflicts preemption). *Chae v. SLM Corp.*, 593 F.3d 936, 941 (9th Cir. 2010). Field and conflicts preemptions are examples of implied preemption because, absent express preemption, there is an inference that Congress left no room for state regulation or that state law actually conflicts with federal law. *Ting v. AT&T*, 319 F.3d 1126, 1136 (2003). Defendants move to dismiss the complaint on the grounds that Plaintiff's claims are expressly and impliedly preempted by the NLEA. (Def.'s Mem. Supp. Mot. Dismiss 11–15.)

The Federal Food, Drug, and Cosmetic Act ("FDCA") vests the FDA with the authority to "protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A). Congress amended the FDCA in 1990, by enacting the Nutrition Labeling and Education Act ("NLEA"), 21 U.S.C. § 343–1. The NLEA was intended to "establish uniform national standards for the nutritional claims and the required nutrient information displayed on food labels." 1990 U.S.C.C.A.N. 3336, 3342. The NLEA also amended the FDCA by adding a preemption provision, codified at 21 U.S.C. § 343–1. This provision expressly preempts state laws addressing certain subjects that are "not identical to" various standards set forth by the FDCA, including the labeling requirements set forth in 21 U.S.C. § 343(k). 21 U.S.C. § 343–1(a)(3). Under FDA regulations, the term "not identical to ...

means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition of labeling" that are "not imposed or contained in the applicable provision[s]." 21 C.F.R. § 100.1(c)(4).

**1. Express Preemption**

The Court's "inquiry into the scope of a statute's pre-emptive effect is guided by the rule that '[t]he purpose of Congress is the ultimate touchstone in every pre-emption case.'" *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) (internal citations omitted). Thus, federal law and state law may "normally coexist" when state law does not impose a different standard from federal law, particularly in "matters of health and safety." *Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 718 (1985); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). "Where a requirement imposed by state law effectively parallels or mirrors the relevant sections of the NLEA, courts have repeatedly refused to find preemption." *Chacanaca*, 752 F. Supp. 2d at 1118 (internal citations omitted).

The inclusion of an express preemption provision that permits state regulations that are identical to federal law demonstrates that state and federal regulations can coexist. *See Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995) ("[A]n express definition of the pre-emptive reach of a statute 'implies' – i.e., supports a reasonable inference that Congress did not intend to pre-empt other matters."). The express savings clause in the amended FDCA provides: "The [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343-1(a)]." PUB. L. NO. 101–535, § 6(c)(1) (21 U.S.C. § 343-1 note).

Accordingly, "plaintiff's claims need not fail on preemption grounds if the requirements they seek to impose are . . . identical to those imposed by the FDCA and the NLEA amendments." *Chacanaca*, 752 F. Supp. 2d at 1119 (internal citations omitted).

**2. Implied Preemption** (Field and Conflicts Preemption)

A federal law impliedly preempts a state law "where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Field preemption may be implied from a "'scheme of federal regulation .

. . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it,' or where an Act of Congress 'touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

"Conflict preemption analysis examines the federal statute as a whole to determine whether a party's compliance with both federal and state requirements is impossible or whether, in light of the federal statute's purpose and intended effects, state law poses an obstacle to the accomplishment of Congress's objectives." *Whistler Invs., Inc. v. Depository Trust and Clearing Corp.*, 539 F.3d 1159, 1166 (9th Cir. 2008) (citing *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000)). The FDCA is intended to "protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2).

Although the FDA has promulgated several food-labeling requirements, Congress has specifically indicated that it does not intend to occupy the field of food and beverage nutritional labeling, and states are permitted to regulate matters covered by the NLEA and its regulations provided that such state laws do not fall within the FDCA's express preemption provisions. *See In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1091 (2008) ("Congress made clear that the preemptive scope of section 343-1 was to sweep no further than the plain language of the statute itself.").

California's food marketing laws fall within a field that states have traditionally occupied. Thus, a presumption exists that Congress did not intend to preempt California law. *See Kroske v. U.S. Bank Corp.*, 432 F.3d 976, 981 (2005) (finding a presumption that Congress did not intend for the National Bank Act to preempt the Washington Law Against Discrimination ("WLAD") because the WLAD was "enacted pursuant to the State's historic police powers to prohibit discrimination on specified grounds").

**3. Preemption and Plaintiff's Claims**

Defendants argue that Plaintiff's claims concerning plant stanol esters, cholesterol, and trans fat are expressly and impliedly preempted by the NLEA. (Def.'s Mem. Supp. Mot. Dismiss 18–22).

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**a. Legal Standard Under Rule 12(b)(6)**

The court must dismiss a cause of action for failure to state a claim upon which relief can be granted. FED. R. CIV. P. 12(b)(6). A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of the complaint. *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). The court must accept all allegations of material fact as true and construe them in the light most favorable to the nonmoving party. *Cedars-Sinai Med. Ctr. v. Nat'l League of Postmasters of U.S.*, 497 F.3d 972, 975 (9th Cir. 2007). Material allegations, even if doubtful in fact, are assumed to be true. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Pleadings that "are no more than conclusions . . . are not entitled to the assumption of truth." *Id.* at 1950.

**b. Plant Stanol Esters Claims**

Pursuant to the FDA's 2000 regulations, "[s]cientific evidence demonstrates that diets that include plant sterol/stanol esters may reduce the risk of [coronary heart disease]" and also "helps to lower blood total and LDL cholesterol levels" if a person consumes "3.4g or more per day of plant stanol esters" in "two servings eaten at different times of the day with other foods." 21 C.F.R. §§ 101.83(a)(3), (b)(2), (c)(2)(i)(G)(2), (c)(2)(i)(H). Food products are eligible to bear these health claims if they contain "[a]t least 1.7g of plant stanol esters" per serving. 21 C.F.R. § 101.81(c)(2)(iii)(A)(2). In addition, the food "must meet the minimum nutrient contribution requirement in § 101.14(e)(6)." 21 C.F.R. § 101.81(c)(2)(iii)(D). Section 101.14(e)(6) prohibits food labels from making health claims unless "the food contains 10 percent or more of the Reference Daily Intake . . . for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition." 21 C.F.R. § 101.14(e)(6)(emphasis added).

In 2003, the FDA issued a letter to Fred L. Shinnick of Cargill Health & Food Technologies which, *inter alia*, lowered the amount of phytosterols required in food because of new scientific evidence. Under the 2003 FDA Letter, an authorized health claim may be made if "(1) the food contains at least 400 mg per reference amount customarily consumed (RACC) of phytoterol . . . (5) the claim specifies that the daily dietary intake of phytosterol that may reduce the risk of CHD is 800 milligrams (mg) or more per day . . . . (RJN, Ex. C.)

Here, Plaintiff alleges that Benecol does not contain the minimum amount of plant stanol esters required per serving and that it also does not meet the minimum nutrient contribution. (Compl. ¶¶ 78, 82.) According to Plaintiff, "Benecol contains .85g of plant stanol esters per serving," which is shy of the 1.7g required pursuant to 21 C.F.R. § 101.81(c)(2)(iii)(A)(2). (*Id.* ¶ 78.) But as noted above, the FDA lowered the amount of phytosterols that was required in 2003. *See also* 21 C.F.R. 101.83(c)(iii)(A), effective July 21, 2005, which is consistent with the FDA 2003 Letter.

In the 2003 FDA Letter, the FDA noted that it was "developing a final rule on this health claim" and "caution[ed] manufacturers that the final rule may differ . . . and that manufacturers would then be required to change their label to conform to the final rule." (RJN, Ex. C.) Until the issuance of a final rule, compliance with the 2003 FDA Letter is all that is required.

In December 2010, the FDA issued a proposed final rule but on February 18, 2011, announced that it would not enforce the proposed final rule until February 21, 2012. Fed. Reg. 9525. Thus, until the FDA publishes a final rule, it plans to exercise enforcement discretion "in a manner that is consistent" with the FDA's letter to Cargill Health and Food Technologies in 2003. The Cargill letter reflects the FDA's position that "[p]ending completion of the final rule, the FDA believes that it would be appropriate to consider the exercise of enforcement discretion with regard to use of the health claim [concerning plant stanol esters] on a wider range of foods." (Def.'s Mem. Supp. Mot. Dismiss Ex. C). The public comments period on this issue closed on April 23, 2012. 77 Fed. Reg. 9842 (2012).

Plaintiff's plant sterol esters claim essentially ask the Court to rule on issues that the FDA has not yet finalized and seeks to impose a different, outdated interim rule requirement for

Defendants from that set forth in the 2003 FDA Letter and 21 C.F.R. 101.83 (2005). Federal agency action short of formal notice and comment rulemaking can preempt state law. *See Holk v. Snapple Bev. Corp.*, 575 F.3d 329 (3d Cir. 2009); *Geier v. Am. Honda*, 539 U.S. 861 (2000). In light of the foregoing and because Benecol's current product labeling is in compliance with the requirement of the 2003 FDA Letter, the Court finds that Plaintiff's claim that Benecol does not contain the sufficient amount of plant stanol esters per serving is preempted.[1]

**c. Cholesterol**

Plaintiff alleges that Benecol's "Proven to Reduce Cholesterol" label is false and misleading. (Compl. ¶¶ 94, 97.) Although Plaintiff acknowledges that "there are studies . . . that plant stanol esters, taken under the correct circumstances, may reduce the risk of heart disease through the intermediary step of reducing LDL cholesterol," he alleges that no studies support the conclusion that Benecol, "as formulated," effectively reduces blood cholesterol. (*Id.* ¶ 94.) Plaintiff also argues that even if Benecol in fact effectively reduces blood cholesterol levels, the "Proven to Reduce Cholesterol" claim is "highly misleading" because "the trans fat would negate much of the claimed impact of Benecol on cholesterol" and may even "expose [the consumer] to increased risk of many other diseases." (*Id.* ¶¶ 97–98.) Further, Plaintiff argues that Benecol's cholesterol claim renders it an improperly-marketed drug because "the statements suggest Benecol may be useful in treating the condition of" high cholesterol. (*Id.* ¶ 102.)

"[S]cientific evidence establishes that including plant sterol/stanol esters in the diet helps to lower blood total and LDL cholesterol levels." 21 C.F.R. § 101.83(b)(2). The regulations allow food products containing plant stanol esters to bear health claims associated with reducing cholesterol and heart disease if they contain the requisite amount of plant stanol esters. *See* 21 C.F.R. § 101.83(c)(2)(i). Further, the FDA authorizes claims "based on, and consistent with, the conclusions" of approved health claims under Section 101.83. *See* 21 C.F.R. § 101.14(d)(2)(i).

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[1] In his complaint, Plaintiff alleges that although Benecol contains 10% of the daily reference intake for vitamin A, Defendants achieve that amount by adding vitamin A to Benecol. This, according to Plaintiff, fails to meet 21 C.F.R. § 101.14(e)(6) and makes Benecol misbranded pursuant to 21 U.S.C. §§ 343(a) and 343(r). (Compl. ¶¶ 82–83.) Neither Plaintiff nor Defendants address this issue in the present motion.

Pursuant to the FDA, a food product can make health claims without its having to be regulated as a drug. "A food or dietary supplement for which a claim . . . is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim." 21 U.S.C. § 321(g)(1).

Plaintiff's cholesterol claims are based on his plant stanol esters health claims, which are authorized by the FDA pursuant to 21 C.F.R. § 101.14(d)(2)(i). The regulations state the minimum amount of plant stanol esters that a product must contain before it can bear health claims, but, contrary to Plaintiff's contention, do not require that products show that they effectively reduce cholesterol "as formulated." (Compl. ¶ 94.) *See* 21 C.F.R. § 101.83(c)(2)(iii)(A)(2). Plaintiff's claim that Benecol is an improperly-marketed drug is also contrary to the FDA's own characterization that Benecol is a food containing phytosterol nutrients. *See* 65 Fed. Reg. 54686–54688 (listing plant stanol esters under the category "The Substances Are Food").

Finally, FDA regulations permit Benecol's use of a heart graphic on the label with an approved health claim. 21 C.F.R. 101.14(a)(1). In this case Benecol is allowed to make a health claim regarding the connection between plant stanol esters and the reduced risk of coronary heart disease.

Plaintiff's claims seek to impose a different requirement than those currently authorized by the FDA. Accordingly, the Court finds that Plaintiff's cholesterol claims are expressly preempted.

**d. Trans Fat**

Plaintiff alleges that Benecol's packaging contains nutrient content claims of "No Trans Fat" or "No Trans Fatty Acids." (Compl. ¶ 108.) According to Plaintiff, while the FDA permits the use of defined nutrient content claims, it has yet to define "No Trans Fat" and "No Trans Fatty Acids." (*Id.* ¶¶ 109–10.) Thus, Plaintiff argues that Benecol is misbranded pursuant to 21 U.S.C. §§ 343(a) and 343(r) because it contains unauthorized nutrient content claims. (*Id.* ¶ 111.) In addition, Plaintiff alleges that these claims are false because Benecol actually contains small amounts of artificial trans fatty acids. (*Id.* ¶ 112.)

Section 343(q) of the FDCA governs "nutrition information" that must be disclosed about certain nutrients in food products. 21 U.S.C. § 343(q); *see Chacanaca*, 752 F. Supp. 2d at 1116. An accompanying regulation requires the disclosure of trans fat content where it is meaningfully present in a food. *Chacanaca*, 752 F. Supp. 2d at 1116; 21 C.F.R. § 101.9(c)(2)(ii). "Trans fat content shall be indented and expressed as grams per serving to the nearest 0.5 (1/2)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content, when declared, shall be expressed as zero." 21 C.F.R. § 101.9(c)(2)(ii). "'[Zero] grams trans fat' is a classic example of a statement that is not a nutrient content claim." *Chacanaca*, 752 F. Supp. 2d at 1117. However, "[i]f such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims." 21 C.F.R. § 101.13(c).

"[A] nutrient content claim[] may not be made on the label or in the labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part." 21 C.F.R. § 101.13(b). Subpart D prescribes requirements for a handful of nutrient content claims but does not include a definition for a "No Trans Fat" claim. (Pl.'s Opp'n 4.) *See* 21 C.F.R. §§ 101.54–101.69 (providing definitions for the terms "high," "good source," "fiber," "more," "high potency," "antioxidant," "light," "no calories," "no sodium," "no fat," etc.).

The NLEA requires that a product label disclose the amount of trans fat per serving by rounding to the nearest 0.5 gram. *See* 21 C.F.R. § 101.9(a)(1). "FDA regulations explicitly define the term "0 Grams of Trans Fat" and the NLEA expressly prohibits any state from directly or indirectly establishing any requirement that is not identical to the relevant federal requirements." *Peviani v. Hostess Brands, Inc.*, 750 F. Supp. 2d 1111, 1119 (C.D. Cal. 2010). Benecol contains less than 0.5 gram of trans fat per serving, and, pursuant to the NLEA's requirements, states "Trans Fat 0g" per serving inside its Nutrition Facts Panel. (Compl. Ex. B.)

Defendants argue that Plaintiff's trans fat claims are expressly preempted by the NLEA because they seek to impose requirements that differ from federal regulations. (Def.'s Mem. Supp. Mot. Dismiss 11.) In *Carrea v Dreyer's Grand Ice Cream, Inc.*, 475 Fed. Appx. 113, 2012

WL 1131526 (9th Cir. 2012), the Court found that a "'0g Trans Fat' statement, located on the front of Drumstick's packaging, are expressly preempted" by the FDCA, as amended by the NLEA. The Court held that the statement was an express nutrient content claim that the FDA "not only permits, 21 C.F.R. § 101.13(i)(3), but further instructs should mirror the Nutrition Facts panel . . .. *Id.* As a result, the Court noted 58 Fed. Reg. 44020, 44024-25 states that "any discrepancy between a nutrient content claim and the Nutrition Facts panel would be 'confusing to consumers," . . . . *Id*. Based on this analysis, the Court concluded that because the Drumstick contained less than 0.5 grams of trans fat per serving, the Nutrition Facts panel was required to express this amount as zero, and "the same rule applies to the statement on the front of Drumstick's packaging." *Id.*, citing 21 C.F.R. § 101.9(c)(2)(II). Thus, a claim based on a statement of "0g Trans Fat" found on the front of a products packaging is expressly preempted by the NLEA.

In the present case, Plaintiff's assert that his claim does not concern the term "0 grams trans fat," but instead, Benecol's packaging states "No Trans Fat" and "No Trans Fatty Acids". In other words, plaintiff is attempting to distinguish "0g trans fat" or "0 grams trans fat", which the FDA permits under 21 C.F.R. § 101.13(i)(3), with Defendants' labeled Benecol's trans fat content, "No Trans Fat" and "No Trans Fatty Acids", thereby avoiding express preemption. The Court does not agree. Making a distinction between "No Trans Fat" and '0 grams trans fat" is unreasonable. The terms are functionally equivalent. A consumer would not be confused by the representation of "No Trans Fat" on the packaging of Benecol with the term "0 grams trans fat" found on the Nutrition Facts panel. Accordingly, the Court finds that Plaintiff's trans fat claims are expressly preempted by the NLEA.

**e. Conclusion**

Accepting all allegations of material fact as true and construing them in the light most favorable to Plaintiff, the Court finds that Plaintiff's state law claims are barred by either express or implied preemption and must be dismissed. Nevertheless, the Court also considers Defendants' argument concerning the primary jurisdiction doctrine.

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**C. Primary Jurisdiction Doctrine**

"The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). "[T]he doctrine is a 'prudential' one, under which a court determines that an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch." *Id.* (internal citation omitted). The doctrine "is to be used only if a claim requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency, and if protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme." *Id.* (internal citation omitted). If the doctrine is applicable, "the court either stays proceedings or dismisses the case without prejudice, so that the parties may seek an administrative ruling." *Id.* at 1115.

A court traditionally weighs four factors to determine whether to apply the primary jurisdiction doctrine: "(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity that (4) requires expertise or uniformity in administration." *Syntek Semiconductor Co., Ltd. v. Microchip Tech., Inc.*, 307 F.3d 775, 781 (9th Cir. 2002).

As stated above, the Court finds that Plaintiff's claims are preempted. But even if they are not preempted, the Court considers whether it would be suitable to defer this issue to the FDA under the primary jurisdiction doctrine in light of the FDA's rulemaking activities over the past twelve years and the extensive amount of scientific research that has been done on the relationship between plant stanol ester consumption and the reduction of the risk of coronary heart disease. *See* 77 Fed. Reg. 9842 (2012).

Here, Plaintiff's claims do not require an agency's expertise to resolve his UCL, CLRA, or warranty claims. The doctrine "is not designed to secure expert advice from agencies every time a court is presented with an issue conceivably within the agency's ambit" but instead "is to

be used only if a claim requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). Plaintiff's claims are premised on whether Benecol's packaging is likely to deceive a reasonable consumer—and "this is not a technical area in which the FDA has greater technical expertise than the courts—[as] every day courts decide whether conduct is misleading." *Lockwood v. Conagra Foods, Inc*., 597 F.Supp.2d 1028, 1035 (N.D.Cal.2009) (declining to apply primary jurisdiction doctrine in false advertising case concerning definition and deceptive use of the term "natural"); *see also Chacanaca v. The Quaker Oats Co.*, 752 F.Supp.2d 1111, 1124 (N.D. Cal. 2010) (plaintiffs advanced a "relatively straightforward claim: they assert that defendant has violated FDA regulations and marketed a product that could mislead a reasonable consumer. This is a question courts are well-equipped to handle.").

Accordingly, the Court will deny Defendants' motion to dismiss Plaintiff's complaint based on the primary jurisdiction doctrine.

**D. Judicial Abstention**

Because the Court has concluded that Plaintiff's claims are barred by preemption, the Court declines to reach these issues under the doctrine of judicial abstention.

**E. Motion to Strike**

Federal Rule of Civil Procedure 12(f) provides that a court "may strike from a pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." FED. R. CIV. P. 12(f). Motions to strike are "generally disfavored because they are often used as delaying tactics and because of the limited importance of pleadings in federal practice." *Rosales v. Citibank*, 133 F. Supp. 2d 1177, 1180 (N.D. Cal. 2001). A federal court will not exercise its discretion under Rule 12(f) to strike a pleading unless the matters sought to be omitted have no possible relationship to the controversy, may confuse the issues, or otherwise prejudice a party. *Ollier v. Sweetwater Union High Sch. Dist.*, 735 F. Supp. 2d 1222, 1223 (2010). "Motions to strike generally will not be granted unless it is clear that the matter to be stricken could not have any possible bearing on the subject matter of the litigation." *In re Facebook PPC Adver. Litig.*,

709 F. Supp. 2d 762, 773 (N.D. Cal. 2010). A court should not strike allegations supplying background or historical material unless it is unduly prejudicial to the opponent. *See LeDuc v. Ky. Cent. Life Ins. Co.*, 814 F. Supp. 820, 830 (N.D. Cal. 1992). When considering a motion to strike, the court "must view the pleadings in a light most favorable to the pleading party." *In re 2TheMart.com, Inc.*, 114 F. Supp. 2d 955, 965 (2000). Finally, rule 12(f) "does not authorize a district court to strike a claim for damages on the ground that such damages are precluded as a matter of law." *Whittlestone, Inc. v. Handi-Craft Co.*, 618 F.3d 970, 971 (2010).

As noted above, a court may strike a pleading that is: (1) redundant, (2) immaterial, (3) impertinent, or (4) scandalous. FED. R. CIV. P. 12(f). An "immaterial" matter has no essential or important relationship to the claim for relief or defenses pleaded. *Cal. Dept. of Toxic Substances Control v. ALCO Pac., Inc.*, 217 F. Supp. 2d 1028, 1032 (C.D. Cal. 2002) (internal citations and quotations omitted). An "impertinent" allegation is neither responsive nor relevant to the issues involved in the action. *Fantasy, Inc. v. Fogerty*, 984 F.2d 1524, 1527 (1993) (rev'd on other grounds). A scandalous pleading is one which "improperly casts a derogatory light on someone, most typically on a party to the action." *Aoki v. Benihana, Inc.*, 2012 WL 899691 at *3 (D. Del. 2012) (internal citations omitted).

**1. Scientific Studies and Other Evidentiary Matter.**

This information is not redundant because it does not appear elsewhere in the complaint. (Compl. ¶¶ 17–74.) Further, it is not immaterial because consumers may have purchased Benecol for its purported health benefits by relying on its representation that Benecol contains "no trans fat." It is not impertinent because trans fat consumption is relevant to consumers' health, especially as to blood cholesterol and heart disease. Lastly, it is not scandalous because these studies explain the general health concerns regarding trans fat intake. Although it casts a derogatory light on Benecol, it is not improper because Defendants do not dispute that Benecol in fact contains artificial trans fat. (Def.'s Mem. Supp. Mot. Dismiss 22.)

Viewing the complaint in the light most favorable to Plaintiff, the Court finds that the evidentiary matter concerning the dangers of trans fat may be relevant in the action. At this point in the litigation, it is not certain that such information "clearly could have no possible bearing on

the subject of the litigation." *Platte Anchor Bolt, Inc. v. IHI, Inc.*, 352 F. Supp. 2d 1048, 1057 (N.D. Cal. 2004).

**2. Disgorgement of Profits.**

As noted above, pursuant to Rule 12(f), a district court may not strike a claim for damages on the ground that such damages are precluded as a matter of law. FED. R. CIV. P. 12(f)*; Whittlestone*, 618 F.3d at 971. As such, the Court denies Defendants' motion to strike Plaintiff's claim for disgorgement because it is an inappropriate decision for the Court to make at this stage of the proceedings.

**3. Misbranded Drug**

Plaintiff alleges that Benecol is a misbranded drug because it made unauthorized health claims regarding its plant stanol esters content, ability to reduce cholesterol, and trans fat content. (Compl. ¶¶ 78–86, 102, 108–12.) As discussed above, the Court finds that the NLEA preempts Plaintiff's claims and therefore dismisses them with prejudice. Thus, Defendants' motion to strike claims is moot.

**F. Request for Judicial Notice**

On a motion to dismiss, a court's review is limited to the complaint and matters judicially noticeable. *MGIC Indem. Corp. v. Weisman*, 803 F.2d 500, 504 (9th Cir. 1986); *see Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1555 n.19 (9th Cir. 1989). A court may take judicial notice of a fact "not subject to reasonable dispute" because the fact is "generally known within the trial court's territorial jurisdiction" or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." FED. R. CIV. P. 201. "The court can take judicial notice of matters of public record, such as . . . records and reports of administrative bodies." *Von Koenig v. Snapple Beverage Corp.*, 713 F. Supp. 2d 1066, 1073 (E.D. Cal. 2010) (taking judicial notice of the FDA's warning letters for purposes of the motion to dismiss because the letters express the FDA's position on the use of the term 'natural' and are matters of public record available on its website). However, a court may decline to take judicial notice of irrelevant facts even if they are matters of public record. *See Ruiz v. City of Santa Maria*, 160 F.3d 543, 548 n.13 (1998).

Plaintiff requests that the Court take judicial notice of sixteen exhibits. (Pl.'s Request for Judicial Notice [Doc. 17-1].) Although Plaintiff cites authority that courts may take judicial notice of the FDA's warning letters because they are public documents, Plaintiff fails to provide reasons for the relevance of each letter. (*Id.* 2.) The warning letters Plaintiff seeks to introduce pertain to foods that are promoted as drugs because they are marketed as products that are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1). The FDA allows foods containing plant stanol esters to bear health claims pursuant to 21 C.F.R. § 101.83. None of the warning letters pertain to foods that contain plant stanol esters.

Accordingly, the Court will deny Plaintiff's request for judicial notice of the sixteen FDA warning letters.

## IV. CONCLUSION

Based on the foregoing, **IT IS ORDERED**:

1. Defendants' motion to dismiss on preemption ground is **GRANTED**;
2. Defendants' motion to strike is **DENIED** in its entirety; and
3. The Clerk of the Court is directed to close this case.

**IT IS SO ORDERED.**

DATED: September 17, 2012

M. James Lorenz
United States District Court Judge

COPY TO:

HON. BARBARA L. MAJOR
UNITED STATES MAGISTRATE JUDGE

ALL PARTIES/COUNSEL